

DETAILED ACTION

Claim Status

1. **Claims 1, 13, and 17-19**, as amended 16 December 2010, are currently pending. **Claims 2-12, 14-16, and 20-21** are cancelled.

Claim Interpretation

2. It is noted that the instant claims are directed to an apparatus. Therefore, regarding limitations recited in the claims which are directed to a manner of operating disclosed apparatus, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

3. Additionally, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. **Claims 1, 13, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 63-56044 in view of Fukasawa et al. (EP 0306613, "Fukasawa").

Regarding **claim 1**, JP 63-56044 discloses a hollow fiber membrane type fluid treatment device (Figure 2), comprising:

- a housing body portion of tubular housing (4) containing a hollow fiber membrane bundle (2)
- a first housing head portion which is connected with one end of the housing body portion and has a resin layer (3) where the hollow fiber membrane bundle is fixed by using a resin composition (3) and a first connection port (13) which serves as a treatment liquid inlet (Figure 2, upper end)
- a second housing head portion which is connected with a second of the housing body portion and has a resin layer where the hollow fiber membrane bundle is fixed by using a resin composition (3) and a second connection port (13) which serves as a treatment liquid outlet (Figure 2, lower end)
- first and second header caps (caps, 5) attached to the first and second housing head portions, respectively, and the first and second header caps having respective treatment target liquid connection ports (8, 9)
- an inner surface of the housing body portion comprises a body straight portion (straight center portion, 4) and an end tapered portion which increases in diameter toward the end face of the housing body portion (tapered ends shown in Figure 2)
- the hollow fiber membranes are arranged so that a distance between the hollow fiber membranes is gradually increased toward the end face of the housing body

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portion as the hollow fiber membranes extend along a taper of the end tapered portions (Figure 2, hollow fibers 2)

- opening ends of the hollow fiber membrane bundle being fixed to an inside of the housing by the resin layers and the opening ends of the hollow fiber membrane bundle facing the respective treatment target liquid connection ports (Figure 2, resin layer 3, facing openings 8, 9)
- the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle (Figure 2, openings 13)

While the reference does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (as evidenced by Fukasawa, pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of JP 63-56044 to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

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While the reference does not explicitly disclose the ratio of the length of the body straight portion to the total length of the end tapered portion being between 0.7 to 20 and the ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion being more than 1 and not more than 3, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and straight body portions as well as the diameters, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (or dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding **claim 13**, JP 63-56044 discloses all of the claim limitations as set forth above. Additionally, the reference discloses the device wherein the tapered portion comprises a first tapered portion located on the body portion side (Figure 2, tapered portion near openings 13) and a second tapered portion located on the treatment liquid inlet side (Figure 2, tapered portions on the side opposing the openings 13). The reference does not explicitly disclose the angle of the first taper angle is smaller than the angle of the second taper angle.

Fukasawa discloses that an off-centered taper on the housing walls adds the benefit of increasing the distance between the side inlet port and the bundle of hollow fiber membranes,

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thereby enlarging the flow area of that part of the flow passage. This annular flow passage allows incoming fluid to be more evenly distributed to the hollow fiber membranes (Figure 3, pg 4/L57 – pg 5/L2).

It would have been obvious to one having ordinary skill in the art at the time of the invention to use an off-centered tapered design on the ends of the housing in the apparatus of JP 63-56044, as taught by Fukasawa, since doing so will enlarge the flow area by the side openings, allowing incoming fluid to be more evenly distributed to the hollow fiber membranes.

Regarding **claim 17**, JP 63-56044 discloses all of the claim limitations as set forth above. Regarding limitations recited in **claim 17** which are directed to a manner of operating disclosed device (e.g. “a urea clearance of 191 to 200 ml/min”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. *See Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

6. **Claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 63-56044 and Fukasawa et al. (EP 0306613, “Fukasawa”), as applied to **claim 1** above, and further in view of Kanno et al. (US 4,201,673, “Kanno”).

Regarding **claims 18-19**, JP 63-56044 discloses all of the claim limitations as set forth above. The reference does not explicitly disclose the device comprising baffle plates provided at positions corresponding to the treatment liquid inlet and the treatment liquid outlet of the tubular

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housing and interspatially from the inner circumference of the tubular housing over the entire inner circumference at a curvature almost along the inner circumference. Further, the reference does not disclose the device wherein the baffle plate gradually increases in diameter toward the end face of the housing.

Kanno discloses a dialyzer with hollow fiber membranes (abstract) which contains a baffle plate (annular rib 15) which increases in diameter toward the end of the housing (see Figures 2 & 3). Kanno teaches that a baffle plate may help avoid channeling and may improve efficiency by allowing fluid to flow over the outermost hollow fibers (C1/L45-60).

JP 63-56044, Fukasawa, and Kanno are analogous because both references are directed to hollow fiber membrane modules.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a baffle plate to the module of JP 63-56044, as taught by Kanno, since doing so may help avoid channeling, thereby improving the efficiency of the device.

Response to Arguments

7. In light of the amendments to **claim 1**, the rejection under JP '527 is no longer applicable.

8. Applicant's arguments filed 3 August 2011 regarding the rejection under JP '044 and Fukasawa have been fully considered but they are not persuasive.

9. Applicant argues that JP '044 merely discloses a fiber bundle that is constricted in the central portion and does not disclose that the distance between the individual hollow fibers increases toward the end face of the housing. This argument is not persuasive because the reference clearly shows that the fibers spread apart at the end tapered portions (Figure 1, where an angle theta is created at point 11, denoting the change in direction of the hollow fiber). This

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is also seen in the second embodiment of the reference (Figure 2, the fiber bundle increases in diameter as it moves toward the end face, thereby increasing the distance between individual fibers).

10. Applicant has continued to argue that the reference do not disclose the specifics of the claimed angles. A declaration has been submitted to further support their argument. The declaration specifically points to Example 8 and comparative example 3. The Applicant states that they have significant results by using an angle as defined by the claim, thus the optimization would be non-obvious. However, the results of presented in the instant specification do not support the full range of the claim limitation and do not support that the improvement was unexpected. The comparative examples in the instant specification are hollow fiber membrane modules having no angle at all (for example, comparative example 3, theta is zero); there is not a single comparative example presented that shows the criticality of the particular range of angles claimed. The references applied all have angled sides (and JP '044 clearly shows a theta value greater than zero), the angle may be optimized based on the properties discussed in the rejection. Where is the evidence which supports that the results of the instant invention are unexpected? Has the problem of the fluid taking a short path through the module been an unsolved problem facing the area of art? Where is the evidence which supports that the particular range of angles claimed is significant? The current evidence presented in the specification merely shows that a module with angled ends has better results/separation properties than a module which is completely straight.

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571)270-7064. The examiner can normally be reached on 7:00am - 3:30pm Monday-Friday (CST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/KRISHNAN S MENON/
Primary Examiner, Art Unit 1777

/K. Z./
Examiner, Art Unit 1777
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